Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Water for Injections Ph Eur.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1mL contains 1g water for injections,
5mL contain 5g water for injections,
10mL contain 10g water for injections,
20mL contain 20g water for injections.

3 PHARMACEUTICAL FORM

Solvent for parenteral use.

A clear liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Water for Injections is used as a vehicle for dilution and reconstitution of suitable medicinal products for parenteral administration.

4.2 Posology and method of administration

Dosage:
The volume given and administration rate are dependent upon the additive.

Administration:
For parenteral use.
The directions for use of the additive will dictate the administration route.
The solution should only be used if it is clear without visible particles.

4.3 Contraindications

Contraindications related to the additive .

4.4 Special warnings and precautions for use

Water for Injections is hypotonic and it should not be administered alone, because it may cause haemolysis.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions related to the additive.

4.6 Fertility, pregnancy and lactation

This solvent does not present any hazard to the pregnant woman, to the foetus or to the breast-fed child, however the hazard depends upon the additive.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

None are known for Water for Injections, so any undesirable effects may be related to the additive.
Intravenous administration can lead to haemolysis if it is administered alone.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

4.9 Overdose

Haemolysis may occur following infusion of large volumes of hypotonic solutions using sterile water for injections as diluent.

The signs and symptoms of overdose may also be related to the nature of the additive. In the event of accidental overdose, the treatment should be discontinued and the patient should be observed for the appropriate signs and symptoms related to the additive administered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvents and diluting agents, incl. irrigating solutions
V07A B01.

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Incompatible with oily liquids.

6.3 Shelf life

5 years.
From a microbiological point of view, the product should be used immediately after opening. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution / dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Unopened product: This medicinal product does not require any special storage conditions.
Opened product: For storage conditions of the opened, reconstituted or diluted medicinal product, see section 6.3.

6.5 Nature and contents of container

Polypropylene ampoules of 5 mL, 10 mL or 20 mL. 5 mL ampoules are packed into cartons of 20 or 50 ampoules. 10 mL are packed into cartons of 20, 50 or 100 ampoules and 20 mL are packed into a carton of 20 ampoules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

After single use, product should be discarded
Any unused product should be discarded.

7 MARKETING AUTHORISATION HOLDER

Noridem Enterprises Ltd
Evagorou & Makariou
Mitsi Building 3, Suit. 115
1065 Nicosia
Cyprus

8 MARKETING AUTHORISATION NUMBER

PA1122/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1 February 2008
Date of last renewal: 25 August 2009

10 DATE OF REVISION OF THE TEXT

March 2018